

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

IN RE: DIGITEK PRODUCTS
LIABILITY LITIGATION

MDL NO.1968

THIS DOCUMENT RELATES TO ALL CASES:

**PRETRIAL ORDER #12
(Stipulated Protective Order)**

I. Scope of Order

- A. Disclosure and discovery activity in this proceeding may involve production of confidential, proprietary, and private information for which special protection from public disclosure and from use for any purpose other than prosecuting this litigation would be warranted. Accordingly, the parties hereby stipulate to and petition the court to enter the following Stipulated Protective Order ("Protective Order" or "Order").
- B. This Protective Order shall govern all hard copy and electronic materials, the information contained therein, and all other information produced or disclosed during this proceeding, including all copies, excerpts, summaries, or compilations thereof, whether revealed in a document, deposition, other testimony, discovery response or otherwise, by any party to this proceeding (the "Supplying Party") to any other party or parties (the "Receiving Party"). This Protective Order is binding upon all parties to the MDL proceeding, including their respective corporate parents, subsidiaries and affiliates and their respective attorneys, principals, agents, experts, consultants,

representatives, directors, officers, employees and others as set forth in this Protective Order.

- C. Third parties who so elect may avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order and thereby become a Supplying Party for purposes of this Protective Order.
- D. The entry of this Protective Order does not preclude any party from seeking a further order of this court under Federal Rule of Civil Procedure 26(c).
- E. Nothing herein shall be construed to affect in any manner the admissibility at trial or any other court proceeding of any document, testimony, or other evidence.
- F. This Protective Order does not confer blanket protections on all disclosures or responses to discovery and the protection it affords extends only to the specific information or items that are entitled to protection under the applicable legal principles for treatment as confidential.

II. Designation and Redaction of Confidential Information

- A. "Confidential Information" as used herein means any information that the Supplying Party believes in good faith constitutes, reflects, discloses, or contains information subject to protection under Federal Rule of Civil Procedure 26(c) or other applicable law, whether it is a document (electronic or otherwise), information contained in a document, information revealed during a deposition or other testimony, information revealed in an interrogatory response or information otherwise revealed. In designating materials as "CONFIDENTIAL," the Supplying Party shall do so in good faith consistent with the provisions of this Protective Order and rulings of the court.
- B. Specific documents and discovery responses produced by the Supplying Party shall,

if appropriate, be designated as "CONFIDENTIAL" by marking the pages of the document that contain Confidential Information as follows: "CONFIDENTIAL" or "CONFIDENTIAL SUBJECT TO PROTECTIVE ORDER."

C. Information disclosed at a deposition taken in connection with this proceeding may be designated as Confidential Information by designating the portions of the transcript in a letter to be served on the court reporter and opposing counsel within thirty (30) calendar days of the Supplying Party's receipt of the final transcript of a deposition. The court reporter will indicate the portions designated as confidential and segregate them as appropriate. Designations of transcripts will apply to audio, video, or other recordings of the testimony. The court reporter shall clearly mark any transcript released before the expiration of the 30-day period as "Confidential -Subject to Further Confidentiality Review." Such transcripts will be treated as Confidential Information until the expiration of the 30-day period. If the Supplying Party does not serve a designation letter within the 30-day period, then the entire transcript will be deemed not to contain Confidential Information and the "Confidential -Subject to Further Confidentiality Review" legend shall be removed.

D. A party in this proceeding may designate as Confidential Information any document or information produced by, or testimony given by, any other person or entity that the party reasonably believes qualifies as such party's Confidential Information under this Protective Order. If any third party produces information that any party in good faith believes constitutes its Confidential Information, the party claiming confidentiality shall designate the information as such within thirty (30) days of its

receipt of such information. Any party receiving information from a third party shall treat such information as confidential during this thirty (30) day period while all parties have an opportunity to review the information and determine whether it should be designated as confidential. Any party designating third party information as confidential shall have the same rights as a Supplying Party under this order with respect to such information.

- E. To the extent that matter stored or recorded in the form of electronic or magnetic media (including information, files, databases or programs stored on any digital or analog machine-readable device, computers, Internet sites, discs, networks or tapes) ("Computerized Material") is produced by any party in such form, the Supplying Party may designate such matters as confidential by cover letter referring generally to such matter. Whenever any party to whom Computerized Material designated as confidential is produced reduces such material to hard copy form, that party shall mark the hard copy form with the "CONFIDENTIAL" designation.
- F. To protect against unauthorized disclosure of Confidential Information, and to comply with all applicable state and federal laws and regulations, the Supplying Party may redact from produced documents, materials or other things, or portions thereof, the following items, or any other item(s) agreed upon by the parties or ordered by the court:
 - 1. The names, street addresses, Social Security or tax identification numbers and other personal identifying information of patients, health care providers, and individuals in clinical studies or adverse event reports. Other general identifying information, however, such as patient or health care provider

numbers, shall not be redacted unless required by state or federal law. To the extent a plaintiff's name is contained in any of these documents, a copy of the documents that have not had the plaintiff(s)' information redacted will be produced directly to counsel for said plaintiff(s);

2. Highly confidential trade secrets such as those related to the formulation of Digitek®, unless such formulation also appears in the ANDA for Digitek;
3. Highly confidential business and proprietary information related to sales data of the named Defendants, except sales data of Digitek;
4. Any information relating to products other than Digitek®, unless manufacturing information about a product other than Digitek is reasonably related to Digitek manufacturing; and
5. The street addresses, Social Security or tax identification numbers and other personally identifying information of employees in any records.

Notwithstanding any of the foregoing provisions, nothing contained herein shall be construed as a waiver of plaintiff's ability to seek an order for good cause shown compelling production of information redacted pursuant to this paragraph.

G. As required under 21 C.F.R. §§ 314.430(e) & (f) and 20.63(f), the names of any person or persons reporting adverse experiences of patients and the names of any patients that are not redacted shall be treated as confidential, regardless of whether the document containing such names is designated as Confidential Information. No such person shall be contacted, either directly or indirectly, based on the information so disclosed without the express written permission of the Supplying Party.

III. Access to Confidential Information

A. In the absence of written permission from the Supplying Party or an order of the court, any Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this proceeding and its contents shall not be disclosed to any person other than:

1. the Receiving Party;
2. counsel for the Receiving Party, including any in-house counsel, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel to whom it is reasonably necessary to disclose the Information for purposes of the litigation;
3. with respect to any Confidential Information produced by any plaintiff or third party with respect to plaintiff, any employee or agent of the Receiving Party to whom it is reasonably necessary to disclose such information;
4. independent consultants and/or experts, whether formally retained or not;
5. stenographic employees and court reporters recording or transcribing testimony in this proceeding;
6. any individual(s) who authored, prepared or previously received the information;
7. the court, any Special Master appointed by the court, any state court conducting related proceedings, and any members of their staffs to whom it is necessary to disclose the information; and
8. vendor agents retained by the parties or counsel for the parties.

B. Before disclosing Confidential Information to any person who is, independent of this litigation, a current employee of, or a consultant to, a pharmaceutical company or pharmaceutical distribution company other than the named Defendants in this MDL proceeding that is marketing, designing, or manufacturing a digitalis or a digoxin product, the party wishing to make such disclosure shall give at least ten (10) days' advance notice in writing to the counsel for the party who designated such information as Confidential Information, stating the names and addresses of the person(s) to whom the disclosure will be made and the nature of his or her affiliation with a pharmaceutical or pharmaceutical distribution company. If, within the 10-day period, the Supplying Party files a motion objecting to the proposed disclosure, then the party seeking disclosure may not disclose any Confidential Information to that person until ten days have elapsed after the appeal period from a court order denying the motion. In making such motion, it shall be the Supplying Person's burden to demonstrate good cause for preventing such disclosure. Before disclosing Confidential Information to any person who is, independent of this litigation, a current employee of, or a consultant to, a pharmaceutical or pharmaceutical distribution company other than the named Defendants in this MDL proceeding (whether or not such company is marketing, designing, or manufacturing a digitalis or a digoxin product), the party wishing to make such disclosure shall give counsel for the party who designated such information as Confidential Information sufficient information concerning the proposed recipient that does not identify the proposed recipient but is sufficient to permit an informed decision to be made with respect to

any potential objection, including at a minimum the name of the pharmaceutical or pharmaceutical distribution company and the nature of the person's relationship thereto. If there is no consent to the disclosure within ten (10) days, the party wishing to make the disclosure may submit the information to the court for a determination of whether the disclosure may be made. The objecting party will have an opportunity to request that the court direct the party wishing to make disclosure to produce additional information about the proposed recipient and to submit any other papers and argument it feels necessary to allow the court to make an informed decision. It shall be the burden of the party seeking to prevent such disclosure to demonstrate good cause for prohibiting disclosure. The party seeking disclosure may not disclose any Confidential Information to that person unless and until the court has permitted such disclosure and ten days have elapsed after the appeal period from any such order. If the court allows disclosure of the Confidential Information, the Information remains Confidential Information and the person shall be bound by this order.

- C. Disclosure of Confidential Information beyond the terms of this Protective Order may be made only if the Supplying Party who designated the material as confidential consents in writing to such disclosure, or if the court, after reasonable written notice to all affected parties, orders such disclosure. The terms of this Order shall not apply to any publicly available information or documents.

IV. Confidentiality Acknowledgment

- A. Before the disclosure of any Confidential Information to any person identified above, each putative recipient of Confidential Information shall be provided with a copy of

this Protective Order, which he or she shall read. Upon reading this Protective Order, such person shall sign an Acknowledgment, in the form annexed hereto as Exhibit A, acknowledging that he or she has read this Protective Order and shall abide by its terms. These Acknowledgments are strictly confidential. Counsel for each party shall maintain the Acknowledgments without giving copies to the other side. The parties expressly agree, and it is hereby ordered that, except in the event of a violation of this Order, they will make no attempt to seek copies of the Acknowledgments or to determine the identities of the persons signing them. If the court finds that any disclosure is necessary to investigate a violation of this Order, such disclosure will be made under a separate court order. Persons who come into contact with Confidential Information for clerical or administrative purposes, and who do not retain copies or extracts thereof, are not required to execute Acknowledgments but must comply with the terms of this Order.

V. Handling of Confidential Information During Sworn Testimony

A. If any party wishes to file, or use as an exhibit or as testimonial evidence at a hearing or trial, any Confidential Information, such party must provide reasonable notice to the Supplying Party of the intended use of Confidential Information. The parties shall then attempt to resolve the matter of continued confidentiality by either (a) removing the "CONFIDENTIAL" marking, (b) creating a mutually acceptable redacted version that suffices for purposes of the case, or (c) conferring about methods to avoid or limit public disclosure of Confidential Information during testimony. If an amicable resolution proves unsuccessful, the parties may present the issue to the court for

resolution. The proponent of continued confidentiality will have the burden of persuasion that the document or material should be withheld from the public record in accordance with (a) Local Rule of Civil Procedure 26.4, (b) the *Administrative Procedures for Electronic Filing in the Southern District of West Virginia* § 11, and (c) controlling precedent. *See, e.g., Press-Enterprise Co. v. Superior Court*, 478 U.S. 1, 8-9 (1986); *Virginia Dept. of State Police v. Washington Post*, 386 F.3d 567,575 (4th Cir. 2004).

VI. Filing of Confidential Information with the Court

A. Without written permission from counsel of record for the Supplying Party, a party may not file in the public record in this proceeding any Confidential Information. A party that seeks to file under seal any Confidential Information must file a Motion to Seal testimony or exhibits in accordance with and subject to local and federal rules. When submitting deposition testimony that has been designated as "Confidential," the submitting party shall propose to submit to the extent reasonably possible only those pages of the deposition transcript that are cited, referred to, or relied on by the submitting party.

VII. Protection and Use of Confidential Information

A. Persons receiving or having knowledge of Confidential Information by virtue of their participation in this proceeding, or by virtue of obtaining any documents or other Confidential Information produced or disclosed under this Protective Order, shall use that Confidential Information only as permitted by this Protective Order. Counsel shall take all reasonable and necessary steps to assure the security of any

Confidential Information and will limit access to Confidential Information to those persons authorized by this Protective Order.

- B. Nothing herein shall restrict any party's counsel from rendering advice to its clients with respect to this proceeding or a related action in which the Receiving Party is permitted by this Order to use Confidential Information and, in the course thereof, rely upon Confidential Information, provided that in rendering such advice, counsel shall not disclose any other party's Confidential Information other than in a manner provided for in this Protective Order.
- C. Nothing herein shall restrict a person qualified to receive Confidential Information under this Protective Order from making working copies, abstracts, digests and analyses of such information for use in connection with this proceeding and such working copies, abstracts, digests and analyses shall be deemed to have the same level of protection under the terms of this Protective Order. A qualified recipient shall at all times keep secure all notes, abstractions, or other work product derived from or containing Confidential Information; shall be obligated to maintain the confidentiality of such work product; and shall not disclose or reveal the contents of said notes, abstractions or other work product after the documents, materials, or other things, or portions thereof (and the information contained therein) and information are returned and surrendered. Nothing in this agreement requires the Receiving Party's counsel to disclose work product at the conclusion of the case.
- D. Nothing contained in this Protective Order shall preclude any party from using its own Confidential Information in any manner it sees fit, without prior consent of any

party or the court.

- E. Any party that is served with a subpoena or other notice compelling the production of discovery materials produced by another party must immediately give written notice of such subpoena or other notice to the original Supplying Party. Upon receiving such notice, the original Supplying Party shall bear the burden of opposing, if it deems appropriate, the subpoena on grounds of confidentiality.
- F. If a Receiving Party learns of any unauthorized disclosure of Confidential Information, it shall immediately (a) inform the Supplying Party in writing of all pertinent facts relating to such disclosure, (b) make its best efforts to retrieve all copies of the Confidential Information, (c) inform the person or persons to whom unauthorized disclosures were made of all the terms of this Order, and (d) request such person or persons execute the Acknowledgment that is attached hereto as Exhibit A.
- G. Within thirty (30) days of the conclusion of any attorney's last case in this proceeding, including any appeals related thereto, at the written request and option of the Supplying Party, such attorney and any persons to whom he or she disclosed Confidential Information under this Order shall return and surrender any Confidential Information or copies thereof to the Supplying Party at the Supplying Party's expense. Such persons shall return or surrender any discovery materials produced by the Supplying Party and any and all copies (electronic or otherwise), summaries, notes, compilations, and memoranda related thereto; provided, however, that counsel may retain their privileged communications, work product, Acknowledgments under this Protective Order, and all court-filed documents even

though they contain discovery materials produced by the Supplying Party, but such retained privileged communications and work product shall remain subject to the terms of this Protective Order. At the written request of the Supplying Party, any person or entity having custody or control of recordings, notes, memoranda, summaries or other written materials, and all copies thereof, relating to or containing discovery materials produced by the Supplying Party shall deliver to the Supplying Party an affidavit certifying that reasonable efforts have been made to assure that all such discovery materials produced by the Supplying Party and any copies thereof, any and all records, notes, memoranda, summaries, or other written material regarding the discovery materials produced by the Supplying Party (except for privileged communications, work product and court-filed documents as stated above) have been delivered to the Supplying Party in accordance with the terms of this Protective Order. In lieu of returning the materials, the Supplying Party may direct that the materials be destroyed in a manner that will protect the Confidential Information, and the destroying party shall certify that it has done so.

VIII. Changes in Designation of Information

- A. Inadvertent production of any document or information without a designation of confidentiality will not be deemed to waive a later claim to its confidential nature or preclude the Supplying Party from designating said document or information as Confidential Information at a later date. Any Supplying Party may designate as Confidential Information or withdraw a Confidential Information designation from any material that it has produced provided, however, that such redesignation shall be

effective only as of the date of such redesignation. Such redesignation shall be accomplished by notifying counsel for each party in writing of such redesignation and providing replacement images bearing the appropriate description. Upon receipt of any redesignation and replacement image that designates material as Confidential Information, the Receiving Party shall (i) treat such material in accordance with this Order; (ii) take reasonable steps to notify any persons known to have possession of any such material of such redesignation under this Protective Order; and (iii) promptly endeavor to procure all copies of such material from any persons known to have possession of such material who are not entitled to receipt under this Protective Order.

B. A Receiving Party does not waive its right to challenge a confidentiality designation by electing not to mount a challenge promptly after the original designation is disclosed. A Receiving Party may challenge a Supplying Party's confidentiality designation or redesignation by notifying the Supplying Party, in writing or voice-to-voice dialogue, of its good faith belief that the confidentiality designation was not proper and must give the Supplying Party an opportunity to review the designated material, to reconsider the circumstances, and, if no change in designation is offered, to explain, in writing within fourteen (14) days, the basis of the designation. If a Receiving Party elects to press a challenge to a confidentiality designation after considering the justification offered by the Supplying Party, the Receiving Party shall, in writing, notify the Supplying Party that a resolution cannot be reached regarding the confidentiality designation of a document, then the

Supplying Party shall, within twenty one (21) days of receiving such notice from the Receiving Party, file and serve a motion that identifies the challenged material and sets forth in detail the basis for the designation. The burden of persuasion in any such challenge proceeding shall be on the Supplying Party. Until the court rules on the challenge, all parties shall continue to afford the material in question the level of protection to which it is entitled under the Supplying Party's designation. If after the expiration of the twenty one (21) days the Supplying Party has not filed a motion with the court, the designation of confidentiality will be removed automatically.

IX. Miscellaneous Provisions

- A. It is expressly understood by and between the parties that in producing Confidential Information in this litigation, the parties shall be relying upon the terms and conditions of this Protective Order.
- B. By written agreement of the parties, or upon motion and order of the court, the terms of this Protective Order may be amended or modified. This Protective Order shall continue in force until amended or superseded by express order of the court, and shall survive and remain in effect after the termination of this proceeding.
- C. Notwithstanding any other provision in this order, nothing in this Order shall affect or modify the named Defendants' ability to review Plaintiffs' information and report such information to any applicable regulatory agencies.

IT IS SO ORDERED.

The court **DIRECTS** the Clerk to file a copy of this order in 2-08-md-1968 which shall apply

to each member Digitek-related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action number 2-09-cv-0093. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at www.wvsd.uscourts.gov.

ENTER: February 5, 2009



Joseph R. Goodwin
Joseph R. Goodwin, Chief Judge

EXHIBIT A
ACKNOWLEDGMENT AND AGREEMENT TO BE BOUND

The undersigned agrees:

I declare under penalty of perjury that I have read in its entirety and understand the Stipulated Protective Order that was issued by the United States District Court for the Southern District of West Virginia on _____ in *In re Digitek Products Liability Litigation*, MDL No. 1968. I agree to comply with and to be bound by all the terms of this Stipulated Protective Order and I understand and acknowledge that failure to so comply could expose me to sanctions and punishment in the nature of contempt. I solemnly promise that I will not disclose in any manner any information or item that is subject to this Stipulated Protective Order to any person or entity except in strict compliance with the provisions of this Order.

I further agree to submit to the jurisdiction of the United States District Court for the Southern District of West Virginia for the purpose of enforcing the terms of this Stipulated Protective Order, even if such enforcement proceedings occur after termination of these proceedings.

I hereby appoint _____ of _____ as my West Virginia agent for service of process in connection with this action or any proceedings related to enforcement of this Stipulated Protective Order.

Date: _____

City and State where sworn and signed: _____

Printed name: _____

Signature: _____